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10/533,080	04/28/2005	Kazuhiko Kato	271511US0PCT	2324

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,080	KATO ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and **RCE** filed on 11/03/10 is acknowledged.

Claims 1 and 11-12 are drawn to non elected invention based on original presentation.

Newly submitted claims 1 and 11-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claims prosecuted were drawn to oral composition where as the new claims are drawn to method of forming light scattering layer…

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 and 11-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2-7, 10 and 16 have been cancelled.

Claims 8-9 remain withdrawn.

Claims **13-15 and 17** are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims **13-15 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP 2000-222707) published 06/02/02, translation provided) by itself or in view of EP 1066823, all references are of record.

Yamagishi teaches a composition for oral cavity making teeth white, smooth and glossy, title and page 3, paragraph [0001]. The composition comprises either itself or 30% aqueous solution of fluorine compound in an amount of 0.02 to 0.7 wt. % (fluorine ion –supplying component in terms of fluorine atom) and acidic compound and its salt having pka of 2.5-6.0 in an amount from 0.1 to 10.5 mol/kg, (see abstract and page 2 and claim 1 of the translation). Claim 1 teaches pH from 3 to 5.5 and acid to be from malic acid to tartaric acid, see claims 1-3. The reference teaches that acid component is one or more of lactic acid, acetic acid, citric acid malic acid, **tartaric acid** and adipic acid, see claim 3 on page 2. The fluorine ion supplying compounds are disclosed in paragraph [0008] such as sodium fluoride, sodium monofluorophosphate etc.

The reference teaches that additional ingredients such as drug-effect ingredient, abrasive, adhesives can be added to the formulation in paragraph [0017]. The composition shown in table 2 of Yamagishi does not show calcium ion. The reference teaches that as salts of acid compounds potassium salts are given, and the reference

also teaches that an acid compound and an alkali may also be formulated separately to form buffer system of the acid compound and its salt in the composition. Sodium hydroxide and potassium hydroxide and typical alkalis can be used, see translation [0012]. The potassium hydroxide thus will provide potassium ions and will read on the claimed potassium ions. In paragraph [0013], the reference teaches that 0.1 to 5 mol/kg of an acid compound and its salt in component (B) (as the total amount of an acid compound and its salt in the invented composition, in other words, acid and salt) is preferably contained from the viewpoint of achieving a beautifying/whitening effect. The molar ratio of acid to salt is preferably 10:1 ~ 1:10 to impart a buffer capacity. The content of water is from 5 to 90% in the composition. The pH of the composition itself or a 30% aqueous solution of composition is from 3 to 5.5. In addition to above components, abrasive, drug-effect ingredient, adhesive, binder and so on can be added in the composition. The composition exhibits solubility for hydroxyapatite and fluoroapatite and therefore colored hydroxyapatite on the tooth surface is dissolved, [0020].

While the reference teaches use of potassium salts, the reference does not specifically exemplify the use of potassium ions. The reference although suggests that drug-effective component or other additives can be used in the formulation.

EP teaches while teaching tooth whitening composition teaches use of potassium salts (which supply potassium ions). The potassium salts are used as desensitizing agents, see abstract and page 3, [0011]. Potassium salt is used in an amount of 0.0001wt % to 10wt. % in [0008].

It would have been obvious to one of ordinary to substitute potassium ions in the teachings of Yamagishi et al. in order to provide desensitizing effect (drug –effective component) motivated by the teachings of secondary reference. Potassium salt is used in an amount of 0.0001wt % to 10wt. % in [0008]. The reference does not teach the exact claimed range of potassium ion, however the reference teaches desensitivity due to potassium ions, thus optimization of amount of potassium ion would have been within the purview of skilled artisan at the time of instant invention absent evidence of any unexpected results. Since the references teach tooth whitening composition, it is the position of the examiner that due to the whitening effect, a light scattering layer would be formed as claimed because the claimed components of the composition are taught by the prior art and one skilled in the art would expect the property of light scattering effect to be associated with the chemical composition of the formulation absent evidence to contrary. Optimization of amounts would have been within the purview of skilled artisan by doing experimental manipulations at the time of instant invention. Regarding calcium ions, it is the position of the examiner exclusion of calcium ions would be obvious to one of ordinary skill in the art because should the effect due to calcium ions is not required, one of ordinary would not include in the composition as it is held that “Omission of an Element and Its Function Is Obvious if the Function of the Element Is Not Desired Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (MPEP 2144). Additionally, the composition shown in table 2 of Yamagishi does not show calcium ion. As such the claimed invention would have been obvious to one of

ordinary skill in the art at the time the invention was made in light of the teachings of the prior art.

Response to Arguments

4. Applicant's arguments filed 11/03/10 have been fully considered but they are not persuasive.

Applicant argues that

(a) JP '721 does not teach potassium ion, and the claimed amount of potassium ion;

(b) the combination of JP '721 and EP '823 is impermissible; and

(c) the claimed oral preparation provides an advantageous result.

The advantageous effect of the claimed oral preparation is that a small amount of calcium phosphate that is present in a small gap between enamel rods of the teeth is turned into fluoride-containing fine particles to form a light scattering layer *inside* enamel which causes an irregular reflection in response to the incident light radiated from the outside. See pages 1-3 of the present specification. Normally, internal discoloration of the teeth is apparent through transparent enamel of the teeth. However, this light scattering layer, which looks white and opaque, shields the yellowish color of the teeth and gives the teeth a white appearance. *Id.* The factors responsible for forming the light scattering layer include, e.g., the components (A), (B) and (C), and a specified pH condition, e.g., see page 10 of the present specification. As shown in the Examples and Comparative Examples of Example B series and Example C series of the present

specification, the light scattering layer is not formed when any of the components (A), (B) and (C) is not included.

The present specification addresses the disclose of JP '721 and describes that the oral preparation of JP '721 forms a layer of calcium fluoride on a surface of the teeth to provide whiteness and gloss (pages 2-3, the bridging paragraph). The composition of JP '721 is used for whitening the surface of the teeth, wherein the exogenous coloring matter adheres to a tooth when a person eats, drinks, e.g., coffee or tea, smokes, etc. ([0002]). The oral preparation of JP '721 comprises a source of fluoride and an organic acid. However, JP '721 does not describe or suggest adding potassium ion. In fact, a potassium ion supplying compound is not used in the Examples of JP '721. Also, J P '721 fails to describe the amount of potassium ion so that a light scattering layer can be formed.

The composition of JP '721 is similar to the composition of the Comparative Examples in Tables B I-B3 of the present specification which do not comprise potassium ion and do not form a light scattering layer inside a tooth, as described on pages 33-34 of the present specification.

These arguments are not persuasive. The JP reference does teach inclusion of potassium ions in form of salt and prior art does teach whitening effect. While it is true that no examples have been provided however the JP reference does teach inclusion of

Potassium salt and thus it is implicit that potassium ions will be provided in composition. The reference also teaches that an acid compound and an alkali may also be formulated separately to form buffer system of the acid compound and its salt in the

composition. Sodium hydroxide and potassium hydroxide and typical alkalis can be used, see translation [0012]. The potassium hydroxide thus will provide potassium ions and will read on the claimed potassium ions. In paragraph [0013], the reference teaches that 0.1 to 5 mol/kg of an acid compound and its salt in component (B) (as the total amount of an acid compound and its salt in the invented composition, in other words, acid and salt) is preferably contained from the viewpoint of achieving a **beautifying/whitening effect.**

Applicant argues that the addition of potassium ion, as in the Inventive Examples in Tables B1-B3, provides the formation of an internal light scattering layer which makes teeth whiter. More specifically with regard to the Examples provided in the present specification, Tables A1-A5 describes different amounts of potassium ion (in addition to 0.13 mol/kg referred to in the Advisory Action). Also, the claimed organic acid is malic and/or tartaric acid, i.e., the organic acids used in the Examples.

These arguments are not persuasive because JP does teach teeth whitening effect and inclusion of potassium ions in form of potassium salt. Patent office is not equipped with laboratory to conduct experiments; burden is on applicant to prove that prior art's composition which is obvious from the teachings does not provide the claimed property. The instant claims are drawn to oral preparation and he prior art makers it obvious to make the claimed composition and thus the discovery of whitening effect is also shown by JP's reference. The unexpected results are intended functional limitation once the oral composition is consumed and the whitening effect is also disclosed by JP's reference.

Applicant argues that the Office has agreed that JP '721 does not teach potassium ion (the OA, page 3) and relied on EP '823 describing a bleaching composition in which potassium ion is added as a desensitizer ([0011]). The Office is of the opinion that adding potassium ion as a desensitizer to the surface whitening composition of JP '721 would have been obvious and would have provided an expected result, e.g., whitening and desensitizing.

(A) In response, it is noted that introducing potassium ion of EP '823 into the whitening composition of JP '721, which provides a gradual formation of calcium fluoride on the surface of the teeth (see [0006]), changes the formation of the surface calcium fluoride layer to the formation of an internal light scattering layer, as demonstrated in the present specification. Thus, the goal of JP '721 of the gradual formation of calcium fluoride on the surface of the teeth cannot be realized with the modification by potassium ion and, therefore, the combination of JP '721 and EP '823 is impermissible.

These arguments are not persuasive because the rejection has been modified to include the teachings where JP teaches to include alkali salt such as potassium salt, thus will provide potassium ions.

Applicant argues that (B) EP '823 and JP '721 do not describe or suggest that when the oral preparation is applied to the teeth, wherein an endogenous colored substance is deposited in the depth of the enamel, a light scattering layer that masks the deposited endogenous colored substance is formed inside the enamel of the teeth. More specifically, when the claimed oral preparation is applied to the teeth, fluoride-containing fine particles enter a small gap between enamel rods to form a light

scattering layer which causes an irregular reflection in response to the incident light radiated from the outside, and as a result, the endogenous colored substance deposited inside the enamel is masked by the light scattering layer which looks white and opaque. Thus, the teeth look white without removing the endogenous colored substance. A person skilled in the art would not have reasonably expected such an advantageous effect based on the disclosure of the cited references.

These arguments are not persuasive because while it is true that such light scattering layer is formed, however, the prior art teaches inclusion of all the components for teeth whitening purpose and since the claims are drawn to oral preparation and not to method of forming light scattering layer..., the intended functional limitation will be obvious over the teachings of prior art.

Applicant argues that the composition disclosed in EP '823 is a dental bleaching composition which comprises carbamide peroxide as an essential component. Carbamide peroxide is an unstable substance. As described in paragraph [0028] of EP '823, carbamide peroxide is unstable when water is previously mixed with the composition, and the composition has to be mixed with water at the time of using the composition. In addition, carbamide peroxide cannot stably exist in compositions at a pH 3 to 5.5. EP '823 does no description using an acid; the compositions of EP '823 are neutral and all of the bleaching agents used in the Examples are also neutral. In contrast, the compositions of JP '721 are acidic and have a pH 3-5.5.

The bleaching agent of EP '823 and the oral composition of JP '721 have very different pH ranges, and the pH of the agent of EP '823 and the composition of J P '721

were adjusted to specific ranges to fulfill different goals specific to each of EP '823 and JP '721. Therefore, a skilled artisan would not have been motivated to combine various components of the bleaching agent of EP '823 and the oral composition of JP '721 that have very different pH ranges with a reasonable expectation of improving (or preserving) the properties of the oral composition of JP '721. Thus, the claimed oral preparation which has a pH 3-5.5 and comprises a specific acid, specific fluoride ion supplying compound, potassium ion and water as essential components would not have been obvious over JP '721 and EP '823.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case EP has been cited for potassium ions in oral formulation and motivation to add potassium ions will be for desensitizing effect, since JP suggests addition of drug-effective additives and other conventional additives in oral formulation, one would be motivated to add potassium ions with reasonable expectation of success. Applicant's motivation need not be same as examiners motivation to combine the teachings of references. Instant claims are drawn to oral preparation and light scattering effect argued is intended functional limitation once the preparation is applied to teeth.

Applicant argues that (D) Further, by using a large amount of potassium ion (C), the claimed oral preparation and method allow promoting the formation of a light scattering layer inside the enamel of the teeth and decreasing the amount of (B) to 0.03

to 0.5 mol/kg (e.g., in the Examples of the present specification, the upper limit is 0.15 mol/kg). As a result of the decreased amount of (B), the composition has good flavor. This result would not have been obvious based on the disclosure of the cited references. JP '721 does not describe using a large amount of(C) and uses a large amount of (B), i.e., 0.1-5 mol/kg (0.4-1.5 mol/kg in the Examples).

In response to applicant arguments that the instant composition has good flavor , it is the position of the examiner that good flavor is a relative term and depends upon person to person.

Applicant argues that JP '721 addresses diminishing sensitivity of teeth in the Examples, e.g., paragraph [0028] and Tables 1-3 (please, see [0034] of US 2003/0124068 as an English equivalent). It is described that the composition of Examples 3-1 - 3-4 when used for one month provided the alleviation of pain which was sensed upon drinking cold water.

These arguments are not persuasive to overcome the rejection because JP has been combined with EP reference for inclusion of potassium because JP suggests those drug-effective ingredients and other components can be added and EP teaches benefit of desensitization.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612